



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: State Board of Health

- ☒ Preproposal Statement of Inquiry was filed as WSR 05-23-151 ; or
☐ Expedited Rule Making--Proposed notice was filed as WSR _____; or
☐ Proposal is exempt under RCW 34.05.310(4).

- ☒ Original Notice
☐ Supplemental Notice to WSR _____
☐ Continuance of WSR _____

Title of rule and other identifying information: (Describe Subject) Amending WAC 246-101, Section 201 - Notifiable Conditions and Laboratories and Sections 520 and 635 - Special Conditions - AIDS and HIV. Names Retention of Asymptomatic HIV Case Reports and Expanded HIV Laboratory Test Reporting.

Hearing location(s):

Red Lion Hotel Seattle Airport,
18220 International Blvd.
Seattle, Washington 98188

Date: June 14, 2006 Time: 1:30 p.m.

Date of intended adoption: June 14, 2006

(Note: This is NOT the effective date)

Submit written comments to:

Name: Maria Courogen
Address: DOH Office of Infectious Disease and Reproductive Health,
PO Box 47844, Olympia, WA 98504-7844

e-mail <http://www3.doh.wa.gov/policyreview/>

fax (360)586-5440 by (date) June 5, 2006

Assistance for persons with disabilities: Contact

Harla Eichenberger by June 1, 2006

TTY () 711 or (800) 833-6388(TDD)

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposed rule revision is to: 1) retain HIV case reports by name through a confidential name-based reporting system; and 2) expand HIV laboratory reporting to include all HIV-related laboratory test results. The effect of this proposed rule revision will be to: 1) enhance HIV reporting accuracy to determine service delivery needs; 2) maintain eligibility for Ryan White CARE Act (RWCA) funding through state-level names retention; and 3) provide streamlined control of HIV by local-level names retention. Changes to existing rules include: a) requiring that laboratories report all HIV-related laboratory values to the Department of Health; b) requiring the Department to retain asymptomatic HIV case reports by name; c) permitting local health jurisdictions (LHJs) to retain asymptomatic HIV case reports by name; d) establishing minimum security and confidentiality standards for retaining asymptomatic case reports by name; e) requiring biennial review of LHJ security measures by the Department; and f) requiring a report to the Board of Health by December 2007 on the impact of the name reporting system.

Reasons supporting proposal: The CDC has clearly communicated that only HIV case data reported through a name-based system will be accepted. Washington currently uses a name-to-code system and HIV case reports are not included in the national database. In Fiscal Year 2007, RWCA funding will be calculated on the proportion of states' HIV cases (not just AIDS). The CDC and Council of State and Territorial Epidemiologists recommend expanded lab reporting to enhance HIV reporting accuracy and to determine service delivery needs. This revision will also decrease the burden of labs to sort tests based on certain values.

Statutory authority for adoption: RCW 70.24.125

Statute being implemented: 70.24.125

Is rule necessary because of a:

- Federal Law? ☐ Yes ☒ No
Federal Court Decision? ☐ Yes ☒ No
State Court Decision? ☐ Yes ☒ No

If yes, CITATION:

DATE

NAME (type or print)

Craig McLaughlin

SIGNATURE

TITLE

Executive Director

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

MAY 3 2006

TIME

WSR

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(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

Name of proponent: (person or organization) Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Maria Courogen	DOH/ IDRH, 111 Israel Road, Tumwater WA	(360)236-3458
Implementation..... Maria Courogen		()
Enforcement..... Maria Courogen		()

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

☒ No. Explain why no statement was prepared.

A Small Business Economic Impact Statement is not required under RCW 19.85.030, the rule does not impose more than minor costs on businesses.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Harla Eichenberger

Address: DOH Office of Infectious Disease and Reproductive Health, PO Box 47840, Olympia, WA 98504-7840

phone (360) 236-3424

fax (360)236-3400

e-mail Harla.Eichenberger@doh.wa.gov

☐ No: Please explain:

AMENDATORY SECTION (Amending WSR 05-03-055, filed 1/11/05, effective 2/11/05)

WAC 246-101-201 Notifiable conditions and laboratories. This section describes the conditions about which Washington's laboratories must notify public health authorities of on a statewide basis. The board finds that the conditions in the table below (Table Lab-1) are notifiable for the prevention and control of communicable and noninfectious diseases and conditions in Washington. The board also finds that submission of specimens for many of these conditions will further prevent the spread of disease. Laboratory directors (~~shall~~) must notify public health authorities of positive cultures and preliminary test results as individual case reports and provide specimen submissions using procedures described throughout this chapter. Local health officers may require additional conditions to be notifiable within the local health officer's jurisdiction.

WAC 246-101-205, 246-101-210, 246-101-215, 246-101-220, 246-101-225, and 246-101-230 also include requirements for how notifications and specimen submissions are made, when they are made, the content of these notifications and specimen submissions, and how information regarding notifiable conditions cases must be handled and may be disclosed.

Table Lab-1 (Conditions Notifiable by Laboratory Directors)

Notifiable Condition	Time frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Arboviral Disease (Isolation; Detection of Viral Nucleic Acid or Antibody)	2 days	√		
Blood Lead Level	Elevated Levels - 2 Days Nonelevated Levels - Monthly		√	
Botulism (Foodborne)	Immediately	√		Serum and Stool - If available, submit suspect foods (2 days)
Botulism (Infant)	Immediately	√		Stool (2 days)
Botulism (Wound)	Immediately	√		Culture, Serum, Debrided tissue, or Swab sample (2 days)
Brucellosis (<i>Brucella</i> species)	2 days	√		Subcultures (2 days)

Notifiable Condition	Time frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
CD4+ (T4) lymphocyte counts ((less than 200)) and/or CD4+ (T4) ((percents less than fourteen percent of total lymphocytes)) (patients aged thirteen or older)	Monthly	Only when the local health department is designated by the Department of Health	√ (<u>Except King County</u>)	
<i>Chlamydia trachomatis</i> infection	2 days	√		
Cholera	Immediately	√		Culture (2 days)
Cryptosporidiosis	2 days	√		
Cyclosporiasis	2 days	√		Specimen (2 days)
Diphtheria	2 days	√		Culture (2 days)
Disease of Suspected Bioterrorism Origin (examples): • Anthrax • Smallpox	Immediately	√		Culture (2 days)
Enterohemorrhagic <i>E. coli</i> (shiga-like toxin producing infections only) such as <i>E. coli</i> O157:H7 Infection	2 days	√		Culture (2 days)
Gonorrhea	2 days	√		
Hepatitis A (IgM positive)	2 days	√		
Hepatitis B	Monthly	√		
Hepatitis C	Monthly	√		
Human immunodeficiency virus (HIV) infection (((including)) <u>for example</u> , positive Western Blot assays, P24 antigen or viral culture tests)	2 days	Only when the local health department is designated by the Department of Health	√ (Except King County)	
Human immunodeficiency virus (HIV) infection (((positive results on HIV nucleic acid tests (RNA or DNA))) <u>all viral load detection test results - detectable and undetectable</u>)	Monthly	Only when the local health department is designated by the Department of Health	√ (Except King County)	
Listeriosis	2 days	√		
Measles (rubella)	Immediately	√		Serum (2 days)

Notifiable Condition	Time frame for Notification	Notifiable to Local Health Department	Notifiable to Department of Health	Specimen Submission to Department of Health (Type & Timing)
Meningococcal disease	2 days	√		Culture (Blood/CSF or other sterile sites) (2 days)
Pertussis	2 days	√		
Plague	Immediately	√		Culture or other appropriate clinical material (2 days)
Rabies (human or animal)	Immediately	√ (Pathology Report Only)		Tissue or other appropriate clinical material (Upon request only)
Salmonellosis	2 days	√		Culture (2 days)
Shigellosis	2 days	√		Culture (2 days)
Syphilis				Serum (2 days)
Tuberculosis	2 days		√	Culture (2 days)
Tuberculosis (Antibiotic sensitivity for first isolates)	2 days		√	
Tularemia				Culture or other appropriate clinical material (2 days)
Other rare diseases of public health significance	Immediately	√		

Additional notifications that are requested but not mandatory include:

(1) Laboratory directors may notify either local health departments or the department or both of other laboratory results through cooperative agreement.

(2) Laboratory directors may submit malaria cultures to the state public health laboratories.

AMENDATORY SECTION (Amending WSR 05-11-110, filed 5/18/05, effective 6/18/05)

WAC 246-101-520 Special conditions--AIDS and HIV. (1) The local health officer and local health department personnel shall maintain individual case reports for AIDS and HIV as confidential records consistent with the requirements of this section. The local health officer and local health department personnel ((shall)) must:

(a) Use identifying information on HIV-infected individuals only:

(i) For purposes of contacting the HIV-positive individual to

provide test results and post-test counseling; or

(ii) To contact persons who have experienced substantial exposure, including sex and injection equipment-sharing partners, and spouses; or

(iii) To link with other name-based public health disease registries when doing so will improve ability to provide needed care services and counseling and disease prevention; or

(iv) As specified in WAC 246-100-072; or

(v) To provide case reports to the state health department.

~~(b) ((Destroy case report identifying information on asymptomatic HIV-infected individuals received as a result of this chapter within three months of receiving a complete case report.~~

~~(c))~~ Maintain HIV case reports in secure systems that meet the following standards and are consistent with the 2006 Security and Confidentiality Guidelines developed by the Centers for Disease Control and Prevention:

(i) Secure systems must be described in written policies that are reviewed annually by the local health officer;

(ii) Access to case report information must be limited to health department staff who need it to perform their job duties and a current list of these staff must be maintained by the local health officer;

(iii) All physical locations containing electronic or paper copies of surveillance data must be enclosed in a locked, secured area with limited access and not accessible by window;

(iv) Paper copies or electronic media containing surveillance information must be housed inside locked file cabinets that are in the locked, secured area;

(v) A crosscut shredder must be available for destroying information and electronic media must be appropriately sanitized prior to disposal;

(vi) Files or data bases containing confidential information must reside on either stand-alone computers with restricted access or on networked drives with proper access controls, encryption software and firewall protection;

(vii) Electronic communication of confidential information must be protected by encryption standards that are reviewed annually by the local health officer;

(viii) Locking briefcases must be available for transporting confidential information;

(c) Cooperate with the department of health in biennial review of system security measures described in (b) of this subsection.

(d) Destroy documentation of referral information established in WAC 246-100-072 ((and this subsection)) containing identities and identifying information on HIV-infected individuals and at-risk partners of those individuals immediately after notifying partners or within three months, whichever occurs first unless such documentation is being used in an investigation of conduct endangering the public health or of behaviors presenting an imminent danger to the public health pursuant to RCW 70.24.022 or 70.24.024.

~~((d))~~ (e) Not disclose identifying information received as

a result of this chapter unless:

(i) Explicitly and specifically required to do so by state or federal law; or

(ii) Authorized by written patient consent.

(2) Local health department personnel are authorized to use HIV identifying information obtained as a result of this chapter only for the following purposes:

(a) Notification of persons with substantial exposure, including sexual or syringe-sharing partners;

(b) Referral of the infected individual to social and health services;

(c) Linkage to other public health data bases, provided that the identity or identifying information on the HIV-infected person is not disclosed outside of the health department; and

(d) Investigations pursuant to RCW 70.24.022 or 70.24.024.

(3) Public health data bases do not include health professions licensing records, certifications or registries, teacher certification lists, other employment rolls or registries, or data bases maintained by law enforcement officials.

(4) Local health officials will report (~~((asymptomatic))~~) HIV infection cases to the state health department (~~((according to a standard code developed by the state health department))~~).

(5) Local health officers (~~((shall))~~) must require and maintain signed confidentiality agreements with all health department employees with access to HIV identifying information. These agreements will be renewed at least annually and include reference to criminal and civil penalties for violation of chapter 70.24 RCW and other administrative actions that may be taken by the department.

(6) Local health officers (~~((shall))~~) must investigate potential breaches of the confidentiality of HIV identifying information by health department employees. All breaches of confidentiality (~~((shall))~~) must be reported to the state health officer or their designee for review and appropriate action.

(7) Local health officers and local health department personnel must assist the state health department to reascertain the identities of previously reported cases of HIV infection.

AMENDATORY SECTION (Amending WSR 00-23-120, filed 11/22/00, effective 12/23/00)

WAC 246-101-635 Special conditions--AIDS and HIV. The following provisions apply for the use of AIDS and HIV notifiable conditions case reports and data:

(1) Department personnel (~~((shall))~~) must not disclose identifying information received as a result of receiving information regarding a notifiable conditions report of a case of AIDS or HIV unless:

- (a) Explicitly and specifically required to do so by state or federal law; or
 - (b) Authorized by written patient consent.
- (2) Department personnel are authorized to use HIV identifying information received as a result of receiving information regarding a notifiable conditions report of a case of AIDS or HIV only for the following purposes:
- (a) Notification of persons with substantial exposure, including sexual or syringe-sharing partners;
 - (b) Referral of the infected individual to social and health services; and
 - (c) Linkage to other public health data bases, provided that the identity or identifying information on the HIV-infected person is not disclosed outside of the health department.
- (3) For the purposes of this chapter, public health data bases do not include health professions licensing records, certifications or registries, teacher certification lists, other employment rolls or registries, or data bases maintained by law enforcement officials.
- (4) The state health officer (~~shall~~) must require and maintain signed confidentiality agreements with all department employees with access to HIV identifying information. These agreements will be renewed at least annually and include reference to criminal and civil penalties for violation of chapter 70.24 RCW and other administrative actions that may be taken by the department.
- (5) The state health officer (~~shall~~) must investigate potential breaches of the confidentiality of HIV identifying information by department employees. All breaches of confidentiality shall be reported to the state health officer or their authorized representative for review and appropriate action.
- (6) The department must maintain all HIV case reports in a name-based surveillance system solely for the purpose of complying with HIV reporting guidelines from the federal Centers for Disease Control and Prevention, and must not disclose or otherwise use any information contained in that system for any other purpose, except as expressly permitted by this section.
- (7) Authorized representatives of the department must review available records to reascertain the identities of previously reported cases of asymptomatic HIV infection and retain those cases in a confidential name-based system.
- (8) The department must maintain HIV case reports in secure systems that meet the following standards and are consistent with the 2006 Security and Confidentiality Guidelines developed by the Centers for Disease Control and Prevention:
- (a) Secure systems must be described in written policies that are reviewed annually by the overall responsible party;
 - (b) Access to case report information must be limited to health department staff who need it to perform their job duties and a current list of these staff must be maintained by the overall responsible party;
 - (c) All physical locations containing electronic or paper

copies of surveillance data must be enclosed in a locked, secured area with limited access and not accessible by window;

(d) Paper copies or electronic media containing surveillance information must be housed inside locked file cabinets that are in the locked, secured area;

(e) A crosscut shredder must be available for destroying information and electronic media must be appropriately sanitized prior to disposal;

(f) Files or data bases containing confidential information must reside on either stand-alone computers with restricted access or on networked drives with proper access controls, encryption software and firewall protection;

(g) Electronic communication of confidential information must be protected by encryption standards that are reviewed annually by the overall responsible party;

(h) Locking briefcases must be available for transporting confidential information.

(9) The state health officer or designee must conduct a biennial review of system security measures described in WAC 246-101-520 (1)(b) at local health jurisdictions that are maintaining records by name.

(10) When providing technical assistance to a local health department, authorized representatives of the department may temporarily and subject to the time limitations in WAC ((246-101-525(2))) 246-101-520 receive the names of reportable cases of ((asymptomatic)) HIV infection for the purpose of ((HIV surveillance,)) partner notification, or special studies. Upon completion of the activities by representatives of the state health department, named information will be((:

((a))) provided to the local health department subject to the provisions of WAC ((246-101-525(2)), and

((b) Converted to code and maintained as code only until the person is diagnosed with AIDS)) 246-101-520.

((((7) Within twelve months of the effective date of the HIV infection notification system (by September 1, 2000), established in this chapter,)) (11) By December 2007, the state health officer, in cooperation with local health officers, will report to the board on:

(a) The ability of the HIV reporting system to meet surveillance performance standards established by the federal Centers for Disease Control and Prevention;

(b) The cost of the reporting system for state and local health departments;

(c) The reporting system's effect on disease control activities; ((and))

(d) The impact of HIV reporting on HIV testing among persons at increased risk of HIV infection; and

(e) The availability of anonymous HIV testing in the state.

